UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS Subcategory No. 06-11337 Judge Patti B. Saris
THIS DOCUMENT RELATES TO: *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation Schering-Plough Corporation and Warrick Pharmaceuticals Corporation,* Civil Action No. 09-CV-10547; and *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation, Schering-Plough Corporation and Warrick Pharmaceuticals Corporation,* Civil Action No. 00-10698	

UNITED STATES' SUR-REPLY SUPPORT OF ITS OPPOSITION TO THE MOTION TO APPROVE THE PROPOSED SETTLEMENT BETWEEN SCHERING-PLOUGH CORPORATION, SCHERING CORPORATION, WARRICK PHARMACEUTICALS CORPORATION, CALIFORNIA, FLORIDA AND RELATOR VEN-A-CARE OF THE FLORIDA KEYS

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INTRODUCTION

At its core, the proposed settlement is a brazen attempt to obtain a full federal release for all of Schering/Warrick's drugs, the overwhelming majority of which the Relator did not plead until recently and that were never fully investigated by the government. It is also an attempt to have this Court to make findings of fact and rulings of law, in the absence of anything approaching an adequate evidentiary record, regarding Schering brand drugs on which there is admittedly no case or controversy in the *qui tam* actions, simply so that Schering/Warrick may use these findings and rulings against state plaintiffs in other judicial proceedings. All this Schering/Warrick seek to accomplish through a proposed settlement with the Relator, Ven-A-Care.

For the reasons set forth in the government's Memorandum Opposing the Proposed Settlement (Aug. 28, 2009)(Dkt. 6414, Sub. 392), and below, the United States formally objects to the proposed settlement pursuant to its authority under section 3730(b)(1) of the False Claims Act (FCA). That section gives the government the unfettered and absolute authority to veto the voluntary dismissal of a *qui tam* action. As the Fifth Circuit noted, when it recognized the government's absolute veto authority under section 3730(b)(1), "for more than 130 years, Congress has instructed courts to let the government stand on the sidelines and veto a voluntary dismissal" and that "[i]t would take a serious conflict within the False Claims Act or a profound gap in the reasonableness of the provision for us to be able to justify ignoring this language." *Searcy v. Phillips Electronics N. America Corp.*, 117 F.3d 154, 160 (5th Cir. 1997).

Notwithstanding the absolute nature of the government's veto authority with regard to the voluntary dismissal of *qui tam* actions, the Court need not resolve that question here because the government has provided some of the bases for its objection to the proposed settlement. While

Schering/Warrick take issue with those objections, none of their arguments provides a credible basis to ignore the plain language of section 3730(b)(1), to ignore the government's sound objections, and to order the voluntary dismissal of the Relator's *qui tam* actions with prejudice to the United States as part of the proposed settlement.

ARGUMENT

I. The United States's Consent Is Required For All Voluntary Dismissals of Qui Tam Actions Both Before And After The Initial Sixty Day Seal Period

Schering/Warrick's argument, that the Attorney General's consent is only required during the initial sixty-day seal period, is flatly wrong. Instead, the plain language of section 3730(b)(1), the legislative history, and underlying policy concerns all demonstrate Congress's manifest intention to give the United States complete control over the dismissal of its claims both before and after the initial sixty-day period.

The "first step in interpreting a statute is to determine whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case." *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340, 117 S.Ct. 843, 136, 136 L.Ed.2d 8-08 (1997). Section 3720(b)(1) of the False Claims Act provides that:

> A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

31 U.S.C. § 3730(b)(1).

Nothing on the face of section 3730(b)(1) limits this consent requirement to the initial sixty-day intervention period or provides that thereafter the government may object to, but not veto, the settlement of a *qui tam* action. In the words of both the Fifth and Sixth Circuits, the

"plain language of Section 3730(b)(1) is as unambiguous as one can expect." *Searcy*, 117 F.3d at 159; *see United States ex rel. Doyle v. Health Possibilities*, 207 F.3d 335, 339 (6th Cir. 2000)("This language clearly does not limit the consent provision to the sixty-day intervention period."); *see also United States ex rel. Globe Composite Sol'tns v. Solar Construction*, 528 F.Supp.2d 1, 3 (D. Mass. 2007)("In addition, the statute does not limit the consent requirement to any particular period of time, e.g., the sixty-day seal period."); *but see United States ex rel. Killingsworth v. Northrop Corp.*, 25 F.3d 715 (9th Cir. 1994)(limiting section 3730(b)(1) to the initial sixty-day period.). "If Congress wanted to limit the consent requirement to the period before the United States makes its initial intervention decision, we presume that it knew the words to do so." *Health Possibilities*, 207 F.3d at 339. This Court has also expressed its doubts as to Schering/Warrick's cramped reading of section 3730(b)(1), noting that:

> [The defendant] argues that this requirement under 3730(b)(1) does not apply to the post-intervention time frame . . . However, the plain language of the statute does not include this limitation and several circuit courts have disagreed with Killingsworth and found that the government's consent is required even after the government declines to intervene.

See United States ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Abbott Labs., Inc. (In re. Pharm. Indus. Average Wholesale Price Litig.), 538 F.Supp.2d 392, 398 (D. Mass. 2008).[1]

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[1] In fact, Schering/Warrick's position violates the very "established principle[] of statutory construction" they purport to follow, namely that statutes should be construed so as to not render any provision or phrase superfluous. *See Herman v. Hector I. Nieves Transport, Inc.*, 244 F.3d 32, 36 (1st Cir. 2001)("A primary canon of statutory construction is that a statute should be construed so as to not render any of its phrases superfluous."). To require the Attorney General's consent only during the initial sixty-day period would render the consent provision virtually meaningless. During the initial sixty-day period, a *qui tam* case remains under seal, *see* 31 U.S.C. § 3730(b)(2), and the defendant is usually unaware of its existence. As such, Schering/Warrick's construction would never apply to settlements between the relator and the defendant; it would only apply where the *qui tam* relator decides to dismiss the action voluntarily before the government has rendered its intervention decision. In that case, however, the

The applicable legislative history also belies Schering/Warrick's interpretation. As both the Fifth and Sixth Circuits noted, the consent provision has been in the FCA since it was enacted in 1863. *See Health Possibilities*, 207 F.3d at 342; *Searcy*, 117 F.3d at 159. Notably, that version of the False Claims Act did not permit the United States to intervene in a *qui tam* action – either as a matter of right or for good cause. Thus, the consent provision in the original Act could not have been limited to an initial intervention period, since the original Act did not contain any such period. There is no indication that the 1986 amendments, which added the sixty-day intervention period, were intended to suddenly change the meaning of the consent provision. Indeed, the fact that Congress left the consent provision virtually untouched, strongly suggests to the contrary. The only change Congress made to the consent provision, was to change it from stating that an action could not be "withdrawn and discontinued" without United States's consent, to read that an action could not be "dismissed" without the United States' consent. *See Health Possibilities*, 207 F.3d at 344. Surely Congress would have gone beyond this one superficial change, if it had really intended to alter the meaning of the consent provision and to suddenly limit it to the government's initial intervention period. The fact that Congress did not make any additional amendments to the consent provision, is further evidence that it did not intend to adopt the interpretation now advocated by Schering/Warrick.[2]

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government normally does not need a provision requiring its consent in order to protect its interests since a voluntary dismissal made before the services of the defendant's answer is presumptively without prejudice. *See* Fed. R. Civ. P. 41(a)(1).

[2] Schering/Warrick also argue that by giving the government more tools to manage FCA litigation (e.g., sixty-day period to review *qui tam* cases and to seek extensions, the authority to intervene outright or to take over the case for "good cause" later on), Congress mitigated the government's need for the consent authority beyond the initial sixty-day period. Nothing could be further from the truth. As the Sixth Circuit noted, "[w]ithout the power to consent to a

Nor does, as Schering/Warrick argue, the placement of the consent provision in the FCA provide a credible basis to override the plain language of the statute. *See* Reply Mem. At 7, n.3. Instead, the placement of the consent provision actually emphasizes its importance to the government's ability to monitor *qui tam* actions.

> In terms of statutory context and structure, we note that the consent language appears immediately after the provisos stipulating that a relator acts "for [himself] and for the United States Government," and that "the action shall be brought in the name of the Government." These requirements are indispensable to the qui tam framework, as relators have Article III standing to bring FCA actions only because they act on the government's behalf. The location of the consent provision immediately after the command that the action be brought in the government's name suggests that it is an important component of the government's ability to regulate qui tam actions.

Health Possibilities, 207 F.3d at 342. Notably, Schering/Warrick's cannot point to a shred of evidence to supports its argument that Congress intended by the current placement of the consent provision to modify its longstanding meaning. This argument falls particularly flat given, as noted, that when Congress expressly amended the provision it made no attempt to limit it to the initial sixty-day period.

Without the plain language or legislative history to support its position, Schering/Warrick turn to a parade of contrived conflicts to justify limiting section 3730(b)(1) to the initial sixty-day period. None provides an adequate basis to ignore the plain language of the consent

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proposed settlement of an FCA action, the public interest would be largely beholden to the private relator, who- absent 'good cause' government intervention- would retain sole authority to broadly bargain away government claims." *Id.* at 341**.** There is nothing to suggest, and Schering/Warrick offers no reason, that the government's interest somehow evaporates after the initial sixty-day period. To the contrary, because a dismissal of a relator's action post-declination can bind the United States, as the Supreme Court recently reaffirmed, *see United States ex rel. Eisenstein v. City of New York*, __ U.S. __, 129 S.Ct. 2230 (2009), the government's interest in preventing unjustifiable dismissals of *qui tam* actions is at its zenith during this period.

provision.

For example, Schering/Warrick argue that reading section 3730(b)(1) to extend beyond the initial sixty-day period conflicts with the relator's right to "conduct the action." *See* 31 U.S.C. § 3730(b)(4). The "right to conduct the action" means exactly that: The relator can make decisions regarding discovery, motions, and trial, subject to the right of the government to intervene and to take over the action at a later time upon a showing of good cause." 31 U.S.C. § 3730(c)(3). To allow the government to make an informed decision, the relator is required at the government's request to serve it with copies of all pleadings filed in the action as well as with all deposition transcripts. *Id.* That the relator must obtain the written consent of the Attorney General to dismiss his action, as section 3730(b)(1) requires, is perfectly consistent with the relator's right to conduct the action. *See Health Possibilities*, 207 F.3d at 341 ("Nothing in the [FCA] suggests that the right to 'conduct' an action provides the relator with unilateral and ultimate settling authority."); *Searcy*, 117 F.3d at 160 ("A relator has 'conducted' an action if he devises strategy, executes discovery and argues the case in court, even if the government frustrates his settlement efforts.").

Likewise, the fact that the relator has the authority to settle the case, *see* 31 U.S.C. § 3730(d)(2), hardly means that the relator's settlement authority is unqualified. While the relator has the authority to negotiate an agreement *in principle* to settle the case, it lacks unilateral authority to conclude a final settlement and dismiss the case. Put differently, the relator may settle the case, but it may not dismiss it without the Attorney General and the court's consent. *See Searcy*, 117 F.3d at 160 ("[T]he government's power to block settlements does not mean that the relator will never be the person settling the claim. This provision does not purport to create

an iron-clad 'right to settle.'").

Finally, Schering/Warrick argue that allowing the United States to object to a settlement post declination "leads to practical and very real problems," since the United States cannot force the parties to litigate. This is an academic argument at best because the Relator in this case is prepared to continue litigating against Schering/Warrick should this proposed settlement at issue fall through. Moreover, Schering/Warrick itself acknowledge that this is not, in fact, a dilemma. If a relator does not want to continue litigating, the court may ultimately dismiss for failure to prosecute. That outcome, however, would preclude the possibility of a relator and a defendant settling and trying to dismiss claims that were not part of the action and which the government did not investigate. Nevertheless, the government still believes that it is in the Settling Parties' best interest to resolve this matter in a fashion that addresses the government's concerns. For that reason, the government continues to explore a resolution with Schering/Warrick and the other Settling Parties.

II. The Government's Veto Authority Over Voluntary Dismissals of *Qui Tam* Actions Is Absolute

In order to preserve the government's ability to manage *qui tam* litigation, as well as to protect the public interest, section 3730(b)(1) gives the Attorney General the absolute right to veto the voluntary dismissal of a *qui tam* action.[3] *See Searcy*, 117 F.3d at 158 ("The

[3] Schering/Warrick's arguments regarding involuntary dismissals miss the mark. *See* Reply In Support of Motion For Approval of the Settlement Between California, Florida, and Relator Ven-A-Care of the Florida Keys on Behalf of Itself and the United States, and Schering-Plough, Schering, and Warrick ("Reply Mem.) at 4-5 (Sept. 4, 2009)(Dkt. 6486, Sub. 435). The government does not dispute that section 3730(b)(1) does not extend to involuntary dismissals. Moreover, since the Relator is seeking to voluntarily dismiss its *qui tam* actions, the question of whether that section applies to involuntary dismissals is not before the Court.

Government asks us to sanction an absolute veto power over voluntary settlements in *qui tam* False Claims Act suits. The statutory language appears to grant just that[.]"); *United States ex rel. Kennard v. Comstock Resources, Inc.*, 2009 WL 765002, *11 (E.D. Tex. Mar. 23, 2009)("In fact, [the government] has an 'absolute veto power' over settlements, even if it has not intervened."). In recognition of that absolute veto authority, courts have declined to dismiss with prejudice the claims of the United States absent the government's consent. *See*, e.g., *Solar Construction*, 528 F.Supp.2d at 3 (holding that "the court does not have the authority to dismiss the action with prejudice as to the claims of the United States because the Government has not consented to such a dismissal."); *United States ex rel. Martino v. Intelligent Decisions*, 308 F.Supp.2d 1318, 1322 (M.D. Fla. 2004)(vacating order of voluntary dismissal of declined *qui tam* because the government had not consented to the dismissal).

Courts have long recognized the government's exercise of prosecutorial discretion to be unfettered. "The decision whether to bring an action on behalf of the United States is . . . a 'decision generally committed to [the government's] absolute discretion" for the reasons spelled out in *Heckler v. Chaney*[.]" *Swift v. United States*, 318 F.3d 250, 253 (D.C. Cir. 2003)(internal citations omitted). Courts have found this "absolute discretion" to extend to the False Claims Act. For example, in *Swift v. United States*, 318 F.3d 250 (D.C. Cir. 2003), the court held that section 3730(c)(2)(A) of the FCA grants the government the absolute authority to dismiss a relator's *qui tam* action. *Id.* at 252-253. The Court found that this section, which provides that "[t]he Government may not dismiss [a *qui tam*] action notwithstanding the objections of the [relator] if the [relator] has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion," 31 U.S.C. §

3730(c)(2)(A), did not give "the judiciary general oversight of the Executive's judgment in this regard" . . . and "at least suggest[ed] the absence of judicial restraint." *Id.* at 253. In fact, even though that section granted the relator the right to a hearing, the Court found the hearing served "simply to give the relator a formal opportunity to convince the government not to end the case," *id.* at 253, and was not intended as a vehicle for judicial review of the government's decision.[4] As such, the Court found that "[n]othing in § 3730(c)(2)(A) purports to deprive the Executive Branch of its historical prerogative to decide which cases should go forward in the name of the United States." *Id.*

Section 3730(b)(1) is simply the flip side of the same coin. Just as the FCA empowers the government to decide which cases should proceed, *see* 31 U.S.C. § 3730(c)(2)(A), it equally empowers the government to decide when a *qui tam* action, which is brought in the name of the United States, should be dismissed and all the United States's claims released. As the Sixth Circuit noted, "the power to veto a privately negotiated settlement of public claims is a critical aspect of the government's ability to protect the public interest in qui tam litigation." *Health Possibilities*, at 340. Accordingly, contrary to Schering/Warrick's argument, there is nothing anomalous in Congress's decision to confer on the United States the absolute right to veto inappropriate settlements and such an interpretation is consistent with the government's broad discretion in matters pertaining to its prosecutorial authority generally, and other provisions of the FCA in particular.

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[4] While the government conceded in that case that there could be an exception for "fraud on the court," the court did not rule on whether section 3730(c)(2)(A) allowed for that, or any other type of, exception, given that no evidence of fraud was introduced. *Id.* at 253. Similarly in this case, given that Schering/Warrick have not accused the government of fraud, much less produced evidence to support such a claim, the court need not reach that question.

That section 3730(b)(1) includes the district court does not necessarily mandate a different interpretation or outcome. As noted, section 3730(c)(2)(A) expressly provides for the court to hold a hearing in the event a relator objects to a settlement. Yet, the D.C. Circuit rejected the argument that this requirement reflected Congress's intent to limit the government's prosecutorial discretion or to provide the courts with plenary review of the exercise of that discretion. *See Swift*, 318 F.3d at 253. Similarly, section 3730(b)(1) should not be construed to invite judicial oversight. Given that the government is the "real party in interest" and is in the best position to determine what is in the public's best interest, at least in the context of managing *qui tam* actions, courts should defer to the government when it objects to a voluntary dismissal and can (and should) fulfill this limited consent obligation by noting the government's objections and refusing to dismiss. This is effectively what the Fifth and Sixth Circuits did. While these courts certainly described the government's objections in their factual recitations, *see Health Possibilities*, 207 F.3d at 337-338, *Searcy*, 117 F.3d at 155-156, there is little to suggest that they engaged in the type of review suggested by Schering/Warrick or were prepared to substitute their own judgment for the government's. *See* Reply Mem. at 11.[5] Rather, both courts focused on the narrow legal question of the scope of section 3730(b)(1) and whether it provided the government with the authority to unilaterally veto the voluntary dismissal of a *qui tam* action– which both courts found to be the proper interpretation of section 3730(b)(1).[6]

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[5] While the Fifth Circuit did note the basis of the government's objections in its legal analysis, *see Searcy*, 117 F.3d at 160, nothing in the court's language indicates a review of any kind; just an affirmation of the government's ability to veto the voluntary dismissal pursuant to 117 F.3d at 160.

[6] The government concedes, as it did in the *Swift* matter, that there may be an exception for "fraud on the court." However, given that Schering/Warrick have not accused the

Lastly, it is worth noting that, in sharp contrast to section 3730(c)(2)(A), section 3730(b)(1) does not expressly provide the relator with the opportunity for a hearing. This only bolsters the government's position that its veto authority is absolute and that a hearing– at least in the context of the government's objection to a voluntary dismissal of a *qui tam* action– is completely unsupported and contravenes the plain language of the statute.

III. The Government's Objections Are Grounded In Sound Public Policy

Assuming *arguendo* that section 3730(b)(1) is governed by an arbitrary and capricious standard of review, as suggested by Schering/Warrick, Reply Mem. at 12, the government's objections easily meet that minimal threshold.

A. There Is An Insufficient Evidentiary Record For The Court To Make The Proposed Findings of Fact

The core factual findings sought by Schering/Warrick pertain to Schering's brand drugs alone. *See* Proposed Order Approving Settlement and Dismissal With Prejudice of Schering-Plough Corporation, Schering Corporation and Warrick Pharmaceuticals Corporation (June 26, 2009)(Dkt. #6173, Sub. #231, Exh. C, at 5-6). Notably, neither the Relator nor Schering/Warrick dispute the absence of a "case or controversy," at least with regard to whether the prices Schering reported for its brand drugs give rise under the False Claims Act. Nor do the Relator and Schering/Warrick dispute that the only reason the Relator even mentioned these brand drugs in its amended *qui tam* complaint was to assist with Schering/Warrick's effort to obtain "finality" and to use such findings in the context of state court actions. Against this backdrop, Schering/Warrick and the Relator boldly demand as a condition of the proposed

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government of fraud, much less produced evidence to support such a claim, the court need not reach that question.

settlement that this Court make a wide range of factual findings on what the United States knew or "reasonably considered." In addition to the fact that the FCA plainly does not provide the Relator, much less a defendant, with an opportunity to contest the government's objections to the voluntary dismissal of a *qui tam* action, this Court should decline the Settling Parties' invitation to render what can only be described as an advisory opinion.

Even if the Court were receptive to the idea of making fact findings, either pursuant to section 3730(b)(1) or in assessing the fairness of the proposed settlement, there is simply not a sufficient record for the Court to reach many of the findings and conclusions proposed by Schering/Warrick. At the outset, the government notes that, consistent with its stated position in the AWP MDL, it is not here "challenging *any* of the Court's rulings in other AWP matters in this multi-district litigation." *See* United States' Statement Regarding the Court's Prior Rulings (Dkt. 5492)(emphasis in original). What Schering/Warrick now seek, however, extends beyond the Court's earlier factual findings and legal rulings as well as the discovery taken in the government's intervened cases. For example, Schering/Warrick seek a finding and/or ruling that "government payors, such as Medicaid, did not reasonably consider published AWPs that were generally within 30% of the average selling price for that drug (measured, conservatively by Average Manufacturers Price or AMP calculated in accordance with all applicable HCFA/CMS regulations) to constitute a false or fraudulent statement, or to be misleading, deceptive, or unfair." *See* Proposed Order Approving Settlement and Dismissal With Prejudice of Schering-Plough Corporation, Schering Corporation and Warrick Pharmaceuticals Corporation (June 26, 2009)(Dkt. #6173, Sub. #231, Exh. C, at 5-6).

As a preliminary matter, the AWP MDL focused on Medicare, not Medicaid, which is an

entirely different federal health care program governed by an entirely different statutory regime and reimbursement rules. Moreover, it neither was nor is within the authority of the Centers for Medicare and Medicaid Services (CMS) to render legal opinions on whether a published price was false, fraudulent, misleading, deceptive, or unfair. Lastly, it is farfetched to suggest that CMS would, or even could, have considered, back in the 1990s and early 2000s, a legal standard that this Court only reached in June 2007. Unsurprisingly, the government is unaware of, and Schering/Warrick has not produced, any governmental testimony or evidence obtained during the intervened cases' discovery to support this proposition. For similar reasons, the government does not believe there is an adequate evidentiary record to find that "governmental payors could not have reasonably considered the published WAC for a brand drug where substantial sales were made at WAC (i.e., more than 50% of a drug's sales occurred within 5% of WAC) to constitute a false or fraudulent statement, or to be misleading, deceptive, or unfair." *Id.* at Dkt. #6173, Sub. #231, Exh. C, at 6.

For all the reasons discussed above, the government objects to the Court making the proposed findings of fact or conclusions of law proposed by the Schering/Warrick.

B. The Court Should Not Dismiss The Relator's Qui Tam Actions Because They Involve Drugs That Were Only Recently Added and The Information Provided To The Government Demonstrates the Inadequacy of the Proposed Settlement

As this Court is acutely aware, the story behind every drug is unique, even at the NDC level. It is precisely for this reason that the United States, after an extensive investigation, ultimately intervened on only four Abbott drugs, three Dey drugs, and nine Roxane drugs. Here, notwithstanding that, until a few months ago, the Relator's *qui tam* complaints only alleged fraud in connection with Warrick's two albuterol sulfate products, Schering/Warrick argue that the

government has had ample opportunity to investigate the additional 51 Schering and Warrick drugs and should therefore consent to the release with prejudice of these claims as part of the proposed settlement. This argument is patently absurd on its face.

Schering/Warrick repeatedly highlight the fact that the government requested certain pricing and Medicaid utilization data to supports their argument that the government either did investigate or could have investigated the additional 51 drugs. *See* Reply Mem. at 15-16. As a preliminary matter, Schering/Warrick fail to explain that the government only requested those data in the context of settlement discussions and only because Schering/Warrick demanded that those drugs be included as part of a global resolution. While the government examined those data in the context of settlement, it certainly did not have the benefit of the extensive discovery developed in connection with the albuterol sulfate drugs. Moreover, from what little information the government does possess, the government has serious concerns with regard to the adequacy of the proposed settlement.

For example, even a basic review of Schering/Warrick's damages analysis confirms the government's concerns and reveals several profoundly flawed assumptions that result in an undervaluing of the government's Medicaid claims. First, Schering/Warrick assume that "[o]nce a FUL became effective, all subsequent reimbursements should be excluded from [the] calculations of the federal share of total exposure[.]" Affidavit of Paul Charnetzki ("Charnetzki Affidavit") at 3 (Sept. 4, 2009)(Dkt. 6485, Sub. 435, Exh. A). The only support offered for this assumption is that it "should not be held responsible for CMS's discretion once CMS identified the drugs as a candidate for a FUL." *See* Reply Mem. at 21, n.13. Schering/Warrick completely ignore the "lower of' methodology used by the overwhelming number of States and the fact that

the States relied (and continue to rely) rely upon Warrick's inflated AWPs and WACs in their algorithms and therefore impact the payment to be made for those drugs by the federal government. The relevant question is not whether the state claims were reimbursed with a FUL, but whether a true or accurate AWP or WAC would have resulted in a lower reimbursement for the Warrick generic drugs. Moreover, the States use or non-use of FULs is hardly a defense to Schering/Warrick's liability or the damages it caused. At best, the use of FULs is a mitigation issue, which is not a defense to all damages, especially since the government is not required to mitigate damages. *See, e.g., Toepleman v. United States*, 263 F.2d 697 (4th Cir. 1959); *United States ex rel. Dye v. ATK Launch Systems, Inc.*, 2008 WL 4642164 (D. Utah Oct. 16, 2008).

Second, Schering/Warrick's damages analysis is "based upon the spread between allegedly inflated Medicaid reimbursements for Warrick pharmaceuticals (net of dispensing fees) and but-for reimbursements, calculated using the Average Manufacturer Price ("AMP") with a factor of 250% or 300%, and applying federal medical assistance percentages." Charnetzki Affidavit, at 2. The only support Schering/Warrick offer for its approach is the general Medicaid requirement that reimbursement rates be sufficient to ensure provider participation and therefore patient access to care and services. *See* Reply Mem. at 19 (referring to 42 U.S.C. § 1396a(a)(30)(A)). Schering/Warrick's approach should be roundly rejected. Again, this approach ignores the "lower of" regime employed by the vast majority of states and that damages should therefore be calculated as the difference between what the government actually paid and what it would have paid had Schering/Warrick reported truthful and accurate prices.[7]

[7] There may be limited exceptions to this position to the extent that certain states may not have included the estimated acquisition cost in their "lower of" algorithms when a FUL had been set for a drug.

Second, even assuming that it were appropriate to incorporate the FUL into a damages model, Schering/Warrick provide little justification for why, as a matter of estimating damages suffered by the United States, it would be appropriate to retroactively apply a FUL calculation methodology, which was not codified until 2005 and implemented until 2007, to damages it caused between 1993 and 2003.[8] Even weaker still is Schering/Warrick's assumption that it could somehow apply a standard (i.e., 300% of AMP) that is only under Congressional consideration. *See* Reply Mem. at 20. Instead, if this matter were litigated and the FUL were deemed to be relevant in the assessment of the government's damages, it would be the pre-DRA FUL calculation methodology that would be used.

While the government does not possess Mr. Charnetzki's damages algorithm, it strongly suspects that if Schering/Warrick's two assumptions were disregarded, as they should be, the federal government's damages would be noticeably higher than the range offered by Schering/Warrick. Additionally, even assuming that Schering/Warrick's damages analysis were defensible, the $26.2 to $31.1 million range would still only reflect the federal government's single damages, and not the multiples or civil penalties to which the federal government is entitled under the FCA. *See* 31 U.S.C. § 3729(a)(1). Lastly, Schering/Warrick suggest that there cannot be any Medicaid damages post-2003. *See* Reply Mem. at 17. The government disagrees. The mere fact that the federal government may have developed a better appreciation of general

[8] In 2005, Congress passed the Deficit Reduction Act (DRA), which required that, starting January 1, 2007, Medicaid Federal Upper Limits be calculated based on 250 percent of the lowest AMP, instead of 150 percent of the lowest price published in the national drug pricing publications. Pub. L. No. 109-171, § 6001, 120 Stat. 4, 54-59 (2006)(codified at 42 U.S.C. § 1396r-8). CMS issued the final rule implementing this change in 2007. 72 Fed. Reg. 39,142 (July 17, 2007). That rule went into effect on October 1, 2007. *Id.*

industry practices by the late-1990s is a far cry from the government affirmatively sanctioning Schering/Warrick, or any other pharmaceutical manufacturer, knowingly reporting false and fraudulent prices that it knew would be used for Medicaid drug reimbursement and certainly does not preclude the possibility of FCA liability.

CONCLUSION

For the reasons stated above, the United States respectfully objects to, thus vetoes, the proposed settlement between the Schering-Plough Corporation, Schering Corporation, Warrick Pharmaceuticals Corporation, the States of Florida and California, and Relator Ven-A-Care of the Florida Keys, and the voluntary dismissal of the Relator's *qui tam* actions.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "Opposition to the Motion to Approve the Proposed Settlement Between Schering-Plough Corporation, Schering Corporation, Warrick Pharmaceuticals Corporation, California, Florida, and Relator Ven-A-Care of the Florida Keys" to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Justin Draycott
Justin Draycott

Dated: September 11, 2009